



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,516	11/21/2003	Yiwen Tang	50623.304	3018

Victor Repkin  
Squire, Sanders & Dempsey L.L.P.  
1 Maritime Plaza, Suite 300  
San Francisco, CA 94111

7590

04/18/2008

EXAMINER
----------

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
----------	--------------

1618

MAIL DATE	DELIVERY MODE
-----------	---------------

04/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,516	<b>Applicant(s)</b> TANG ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-8,11-18,20,21,23-25 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,11-18,20-21,23-25 and 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/03/2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,6-8,11,15,17-18,20-21,23-25,28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 01/21229 A1).

Lee teaches an antimicrobial and anti-inflammatory endovascular stent containing a coating comprised of biodegradable polymers including poly(3-hydroxybutyrate-3-hydroxyvalerate) (3-PHB-Co-3-PHV), polycaprolactone (PCL), polyorthoesters, polyglycolic acids, poly lactic acids and blends and combinations

Art Unit: 1618

thereof. See abstract, pag 6 lin 24-29, pag 7 lin 26-31 and claims. Regarding applicant's limitation for the glass transition temperature for first polymer, as disclosed within applicants own specification the Tg of pure PCL is -62°C, thus since Lee teaches the use of PCL the claim limitation is considered met. Furthermore the Tg of a polymer is just a measurable property of that polymer, since the polymers of Lee are the same as applicants claimed first polymer and polymer additive the limitation is inherently met, because it is inherent that the same compound will have the same properties.

Regarding applicant's limitation that the polymeric additive has a degree of crystallization greater than that of the first polymer, once again since the first polymers and polymeric additives are the same it is inherent that the properties of those polymers including the degree of crystallization will be the same for the same compound or polymer. Also since the process of making the coating for a stent and the polymers are being used for the same intended purpose, the degree of crystallization will inherently be the same. Applicants have not set forth in their claims or within the specification how and why their claimed polymers would have a degree of crystallization different than those same polymers known in the art or that are commercially available. The burden is shifted to applicants to show how the degree of crystallization and Tg for their claimed polymers and polymeric additives are different than those polymers taught by Lee.

Claims 1-3,6-8,11-18,20,23-25,28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (EP 0 970,711 A2, cited previously).

Hossainy teaches a process for providing coated stents, the stent coating can be comprised of a PCL and PGA blend. See abstract, [0022], [0025], [0029]-[0031]. The

Art Unit: 1618

coating could be a top coating applied to delay the release of a pharmaceutical agent or the coating can be used as a matrix for the delivery of a pharmaceutically active material. Regarding the limitations on the degree of crystallization and the Tg of the first polymer and polymeric additive, the remarks above regarding Lee are incorporated herein, that is since the polymers of Hossainy are the same as applicants claims the examiner assumes the properties of those polymers will inherently be the same. The burden is shifted to applicants to show that the polymers of Hossainy would not have the same claimed properties of applicant's polymers. Regarding claims 12-14 and 29-31 Hossainy teaches that PCL and glycolide could be used in a blend of from about 35:65 to 90:10, within applicants claimed mass ratio.

Claims 1-3,6-8,11,15,17-18,20,23-25,28 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1, cited previously).

DeSimone teaches an intraluminal prosthesis (including stents) comprised of an erodible polymeric material and a coating which can be comprised of PCL, PGA, PLA and the like and blends thereof. See [0028],[0035]-[0037],[0043] and claims 1,36,38 and 39. Pharmacological agents could be incorporated within the stent or within the coating, since the coating can cover a stent containing the active this would meet the limitation in claim 16 in which a topcoat layer is disposed over a drug reservoir layer. Regarding the limitations on the degree of crystallization and the Tg of the first polymer and polymeric additive, the remarks above regarding Lee are incorporated herein, that is since the polymers of DeSimone are the same as applicants claims the examiner assumes the

Art Unit: 1618

properties of those polymers will inherently be the same. The burden is shifted to applicants to show that the polymers of DeSimone would not have the same claimed properties of applicant's polymers.

Claims 1-3,6-8,11,15,17-18,20,23-25,28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1, '717 from hereon, cited previously).

'717 teaches a coating for implantable devices (including stents), the coating can be comprised of PCL, PGA, PLA and the like, the  $T_g$  of PCL was  $-60^{\circ}\text{C}$ . See abstract, [0014],[0034],[0041],[0050]-[0051] and table 3. The polymeric materials were described as being capable of containing an active agent. Regarding the limitations on the degree of crystallization and the  $T_g$  of the first polymer and polymeric additive, the remarks above regarding Lee are incorporated herein, that is since the polymers of '717 are the same as applicants claims the examiner assumes the properties of those polymers will inherently be the same. The burden is shifted to applicants to show that the polymers of '717 would not have the same claimed properties of applicant's polymers.

### ***Response to Arguments***

Applicant's arguments filed 09/27/2007 have been fully considered but they are not persuasive. Applicants assert that DiSimone, Hossainy and, '717 cannot anticipate their claims because none of the references recite every feature of their claimed invention. Applicants assert that none of the references describe the polymers as having the same  $T_g$  or degree of crystallization presently claimed for the first polymer and polymeric additive.

The relevance of these assertions is unclear. As detailed above it is the position of the examiner that since the polymers taught in the references above are the same as applicants claimed polymers (PCL, PLA and PGA) they will inherently have the same properties including Tg and degree of crystallization. Also since the process of making the coating for a stent and the polymers are being used for the same intended purpose, the degree of crystallization will inherently be the same. Applicants have not set forth in their claims or within the specification how their polymers would have a different degree of crystallization and Tg than those same polymers known in the art or that are commercially available. The burden is shifted to applicants to show that the polymers of the references above would not have the same claimed properties of applicant's polymers.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1618

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618